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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,162	01/31/2002	David M. Harris	HARRIS-00101	2707
28960	7590	03/02/2004	EXAMINER	
HAVERSTOCK & OWENS LLP 162 NORTH WOLFE ROAD SUNNYVALE, CA 94086			ROANE, AARON F	
			ART UNIT	PAPER NUMBER
			3739	6
DATE MAILED: 03/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/066,162

Applicant(s)

HARRIS, DAVID M.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-32 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date 2.   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention I, method of treating an oral cavity or periodontal pocket tissue (claims 1-32) in Paper No. 5 is acknowledged. Additionally, the examiner notes the cancellation of claims 33-42.

**Claims 1-32 are pending and will be examined.**

**Claims 33-42 have been cancelled.**

### ***Claim Objections***

Claim 10 is objected to because of the following informalities:

The phrase "2 Joules or more" should be changed to "2 Joules or more--".

Appropriate correction is required.

***Specification***

The disclosure is objected to because of the following informalities:

- On page 2, line 17, change the phrase “are also can” to –can also--.
- On page 8, line 5, change “10 J/cm2” to –10 J/cm<sup>2</sup>--.
- On page 11, line 13, change “207 an loss” to –207 and loss--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-11, 13-15, 18, 20-24, 26, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rechmann (USPN 5,795,153).

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Regarding claims 1, 3, 18, 20 and 30, Rechmann disclose a method (and a device) for removing (i.e., eradicating) bacterial deposits from teeth comprising locating the pathogens within the oral cavity (inherently part of treatment) and radiating periodontal tissue of the oral cavity with a succession of pulses from a pulsed laser having an energy density of  $10 \text{ J/cm}^2$  or greater per pulse, see abstract, col. 2, lines 19-67, col. 5, line 32 through col. 6, line 57 and figures 1 and 2.

Regarding claim 2, Rechmann further disclose an operating wavelength of 300 nm to 600 nm, see col. 2, lines 19-27.

Regarding claim 4, Rechmann disclose the claimed invention. Inherently the treatment involves tissue volumes.

Regarding claim 5, Rechmann further discloses the treatment a periodontal pocket, see figure 1.

Regarding claims 6, 7 and 26, Rechmann further disclose that this treatment takes place via the use of an optical fiber (26) wherein the distal end of the optical fiber is located in the periodontal pocket, see col. 7, lines 20-32 and figures 5-7.

Regarding claims 9 and 10, Rechmann disclose the claimed invention. The maximum fluence,  $\text{FLU}_{\text{max}}$  of the pulsed laser light is equal to the maximum pulse repetition

frequency,  $f_{\max}$ , times the maximum energy density per pulse, **Density**, times the length of time irradiation,  $T_{\text{radiation}}$  which is given by,  $\text{FLU}_{\max} = f_{\max} \times \text{Density} \times T_{\text{radiation}}$ .

This equals  $600 \text{ J/cm}^2$  for only three seconds of irradiation, see col. 2. Additionally, Rechmann discloses that a “gingival pocket (6)” has a size or depth of “0.5 to 2 mm,” see col. 4, lines 27-39. The examiner estimates the size of the periodontal pocket area irradiated to be roughly from  $0.25$  to  $4 \text{ mm}^2$  and therefore by simply multiplying the above fluence of  $600 \text{ J/cm}^2$  times the irradiated periodontal pocket area of multiplying the  $4 \text{ mm}^2$ , this yields an absorption of 2.4 Joules which meets the further limitation of claim 10.

Regarding claim 11, Rechmann discloses the claimed invention. The pulsed laser has pulse widths of 50 nanoseconds (ns) to 300 ns, see col. 2, lines 51-56. The pulse width (or pulse length) is the time in which the laser is irradiating the tissue. Therefore, the disclosure of Rechmann meets the claimed invention.

Regarding claims 13, 14, 28 and 29, Rechmann further disclose that prevotella intermedia is treated, see col. 5, lines 44-56.

Regarding claims 15 and 30, Rechmann disclose the claimed invention. Rechmann disclose that “black-pigmented bacteroides” are also treated, see col. 5, lines 32-67.

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Regarding claims 21-23, Rechmann discloses the claimed invention. Rechmann treats periodontal pockets formed by the tooth and gum tissue, gum tissue is irradiated with laser energy. The wavelength of laser energy used (300 to 600 nm) is transmitted through as if water was transparent and is absorbed by the bacteria, see figures 3 and 4. Therefore the laser energy easily penetrates (the reduction of laser energy intensity is negligible when the laser energy or light has penetrated a few millimeters.) the soft tissue surrounding the periodontal pocket (since the periodontal tissue consists of mostly water).

Regarding claim 24, Rechmann further discloses a laser source in the form of a Nd:YAG laser, see col. 6, lines 19-22.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153) in view Myers (USPN 6,019,605).

Regarding claims 8 and 27, Rechmann et al. disclose the claimed invention except for explicitly reciting that the diameter of the fiber optic is 0.05 mm to 3.0 mm. Myers discloses a device having a laser and fiber optic and method for treating periodontal disease and teach that “ in order to treat the periodontal disease, a free end 18 of an optical fiber 20 is inserted into the periodontal pocket. The optical fiber preferably has a diameter of between 300 and 600 microns,” see col. 2, lines 33-36. 1 million microns equals 1 meter, or 100 centimeters or 1000 millimeters, therefore Myers discloses a fiber optic that has a diameter range of 0.3 mm to 0.6 mm. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann, as taught by Myers, to use a fiber optic having a diameter in the range of 0.3 mm to 0.6 mm in order to treat the periodontal disease.

Regarding claim 12, Rechmann disclose the claimed invention except for explicitly reciting that debridement is performed prior to laser irradiation. Myers teaches “debridement of the plaque from the teeth as well as diseased soft tissue in the periodontal pocket is performed in the conventional fashion. Following such debridement, however, an optical fiber is inserted into the periodontal pocket and laser radiation is emitted through the optical fiber and against not only the soft tissue but also the plaque within the periodontal pocket. For reasons not entirely understood, such laser radiation of the periodontal pocket following debridement has been found to render the periodontal pocket resistant to subsequent bacterial reinfection of the periodontal pocket,” see col. 1, lines 41-51. Therefore at the time of the invention it would have been



obvious to one of ordinary skill in the art to modify the invention of Rechmann, as taught by Myers, to perform debridement prior to the irradiation of the target tissue in order “to render the periodontal pocket resistant to subsequent bacterial reinfection of the periodontal pocket.”

Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153) in view Hasan et al. (USPN 6,462,070 B1).

Regarding claims 17 and 32, Rechmann et al. disclose the claimed invention except for disclosing that a staining agent is used to stain the bacteria or one or more pathogens. Hasan et al. disclose a method of treating periodontal tissue using laser irradiation and teach the use of photosensitizers (a form of staining agents including methylene blue) to target pathogens, col. 1-11. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Rechmann, as taught Hasan et al., to use photosensitizers (a form of staining agents including methylene blue) to target pathogens.

Claims 16 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153).

Regarding claims 16 and 31, Rechmann et al. disclose the claimed invention except for disclosing that the pigmented fungus is selected from the group consisting of Histoplasma

and *Aspirgillus Niger*. At the time of the invention, it would have been an obvious matter of treatment optimization to one of ordinary skill in the art to also test the pigmented fungus is selected from the group consisting of *Histoplasma* and *Aspirgillus Niger* since they also cause periodontal disease and are sensitive to laser irradiation.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rechmann (USPN 5,795,153).

Regarding claim 25, Rechmann et al. disclose the claimed invention except for disclosing that the energy density is  $17 \text{ J/cm}^2$  per pulse or greater. At the time of the invention, it would have been an obvious matter of treatment optimization to one of ordinary skill in the art to use an energy density of  $17 \text{ J/cm}^2$  per pulse or greater because the higher energy density irradiation of the tissue provides a more thorough eradication of the one or more pathogens.

***Allowable Subject Matter***

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

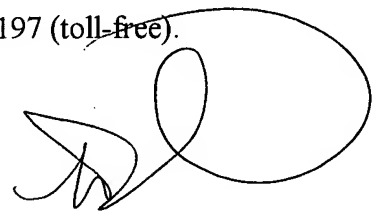
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*  
February 18, 2004



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